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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,428	03/19/2001	Magnus Hook	P06668US03/BAS	6490
881	7590	11/05/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,428

Applicant(s)

HOOK ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-23,26-30,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 15-22,27,28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,23,26,29,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/23/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/04 has been entered.

Amendment

2. Applicant's amendment filed on 8/23/04 is acknowledged.

Status of Claims

3. Claims 2, 24-25, 31 and 32 are canceled.

Claims 1, 23 and 26 have been amended.

New claims 33 and 34 are duplicate claims. Therefore, claim 33 has been added to the elected invention.

Claims 1, 3-14, 23, 26, 29 and 33-34 are under examination as an elected invention, said election made on (6/25/02).

Claims 15-22 and 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Information Disclosure Statement

4. Information Disclosure Statement filed on 8/23/04 is acknowledged and a signed copy is attached to this Office action.

Claim Objections

5. Claim 34 is objected ^{to} as it is a duplicate claim of 33.

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Double Patenting

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 3-14, 23, 26, 29 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/813,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims of the instant application and those of copending Application No. 09/813,820 are drawn to antibodies that bind to collagen binding protein and prevent *S.aureus* infection. Monoclonal and polyclonal antibodies to SEQ.ID.NO: 4 of the copending application bind to amino acids 61-343 of the full length CNA protein and therefore it is obvious that these antibodies bind to CNA 19 peptide of the present application that contains amino acids 151-318 of the full length CNA protein and is within the collagen binding region. Further, the antibodies of the copending application are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat *S.aureus* infection. Therefore, antibodies that bind to CNA 19 peptide read on the antibodies of co-pending application. Antibodies that bind to collagen binding region, amino acid 61-343 would also bind to a smaller CNA 19 peptide that contains amino acids 151-318. The co-pending application

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teaches monoclonal and polyclonal antibodies to SEQ.ID.NO: 4 inhibit the bacterial adhesion to collagen and thereby preventing S.aureus infection. However, the diagnostic kits comprising these antibodies are not taught in the copending application. An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art because these antibodies specifically bind to S.aureus CNA peptide and kits that contain the antibodies which recognize the S.aureus infection would help in diagnosing S.aureus infection conveniently and do not require trained technical support since it comes with instructions to use. Kits were well known in the art for testing or diagnosing varieties of diseases. Instructions are printed matter which have

long been held to distinguish a claimed structure over the prior art only where the printed matter functions in cooperation with the structure. Here there is no such functional cooperation between the printed instructions and the kit's structural components. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep the antibodies as disclosed by the prior art in the form of a compact kit since kits are easy to transport and convenient to work in places (economically under developed countries) with less facilities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 3-14, 23, 26, 29 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent 6,288,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims of the instant application and those of Patent are drawn to antibodies that bind to collagen binding protein and prevent S.aureus infection. The disclosed antibodies to SEQ.ID.NO: 6 of the Patent bind to amino acids 30-531 of the full length collagen binding protein, CNA and therefore it is obvious that these antibodies bind to CNA 19 peptide of

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the present application that contains amino acids 151-318 of the full length CNA protein and is within the collagen binding region. Further, the antibodies disclosed in the patent are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection. Therefore, the instant claims drawn to antibodies that bind to CNA 19 read on the prior art antibodies that bind to collagen binding region (amino acid 30-531) would also bind to a smaller CNA 19 (amino acids 151-318) peptide. The prior art teaches monoclonal and polyclonal antibodies to SEQ.ID.NO: 6 inhibit the bacterial adhesion to collagen and thereby preventing S.aureus infection. However, the prior art does not teach diagnostic kits comprising these antibodies.

An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art because these antibodies specifically bind to S.aureus CNA peptide and would be useful in diagnosing S.aureus infection. Kits containing these antibodies are convenient to work and do not require trained technical support since it comes with instructions to use. Kits were well known in the art for testing or diagnosing varieties of diseases. Instructions are printed matter which have been long been held to distinguish a claimed structure over the prior art only where the printed matter functions in cooperation with the structure. Here there is no such functional cooperation between the printed instructions and the kit's structural components. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep the antibodies as disclosed by the prior art in the form of a compact kit since kits are easy to transport and convenient to work in places with less facilities.

9. Claims 1, 3-14, 23, 26, 29 and 33 are also rejected under 35 U.S.C. 103(a) as being obvious over U.S.Patent 6,288,214

The applied reference has a common inventor (i.e., Hook.M) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only

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under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The prior art teaches antibodies to SEQ.ID.NO: 6. These antibodies bind to amino acids 30-531 of the full length CNA protein and therefore it is obvious that these antibodies bind to CNA 19 peptide that contains amino acids 151-318 of the full length CNA protein and prevent S.aureus infection. Further, the antibodies taught by the prior art are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection. The prior art teaches monoclonal and polyclonal antibodies that bind to SEQ.ID.NO: 6, which inhibit the bacterial adhesion to collagen. The prior art monoclonal and polyclonal antibodies inhibit the bacterial adhesion to collagen, i.e., antibody capable of displacing S.aureus to collagen (see abstract, figures 5-7 and columns 15-19 and claims). Further the prior art teaches antibodies prevent S.aureus infection (i.e., antibody capable of displacing S.aureus to collagen, see figures 7- 8) and other related bacterial colonies (column 4, lines 45-50). Therefore, the

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disclosed antibodies are cross-reactive to *S.epidermis*. The prior art also teaches diagnostic kits comprising the antibodies (column 26). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the antibodies of the prior art because the antibodies disclosed specifically bind to collagen binding region (amino acids 30-531) would also bind to smaller CNA peptide that contains amino acids 151-318 and is within the collagen binding region. An artisan of ordinary skill would have been motivated to use the antibodies disclosed because it would have helped in diagnosing and treating *S.aureus* or *S.epidermis* infections. The claimed invention is *prima facie* obvious in view of Hook et al absent any convincing to the contrary.

Applicants' arguments filed on 8/23/04, have been fully considered but they are not deemed to be persuasive.

Applicant states that an isolated antibody which recognizes the CNA 19 region, amino acids 151-318 of the collagen binding domain from the *S. aureus* CNA protein is cross reactive to *S.epidermidis* and it is an unexpected beneficial result as shown in the accompanying Declaration provided by Dr Magnus Hook. Further applicant explains the binding properties of these bacteria are different. Applicant states that the binding protein of *S.epidermidis* GehD Lipase enzyme differs from CNA19. However, the claimed antibody is an unexpected result over the prior art. Finally applicant states that the examiner is totally inaccurate and has no basis in stating that antibodies bind to the full length protein binds to the CNA19 region, amino acids 151-318 of the collagen binding domain. No prior art antibodies exhibited the unexpected cross- reactivity of the antibodies to the CNA -19 region. Accordingly, these references would not anticipate or render the present claims obvious.

The examiner carefully reviewed the declaration submitted by Dr Magnus Hook and understands and respects his contribution to the art. However, the claims are drawn to an

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antibody, which cross-reacts to *S.epidermidis* and *S.aureus*. The claims do not recite the structural differences of the protein to which the antibody binds as discussed by the applicant. The claims do not set forth the binding regions of the cross reactive antibody to which *S.epidermidis* and *S.aureus* bind. Please note, none of the claims recite that the claimed antibody recognizes GehD Lipase enzyme on *S.epidermidis* and the GehD recognized by the antibody to CNA19 has a circular dichroism spectra that differs from that of CNA. Applicant keeps on arguing about the limitations such as structural differences of proteins which are not set forth in the claims.

Further, applicant (Declaration) provided Appendix A and B, references from *Infection and Immunity* 49 (3): 700-708 (Appendix A) and *J. Biol. Chem.* 277(45): 43017-43023 (November 8, 2002) and Appendix B (*J. Biol. Chem.* 277(45): 43017-43023) to show the differences between *S. aureus* and *S. epidermidis* surface antigens.

The examiner has reviewed the article Appendix A and understands that the clumping factor component could be eluted from *S.aureus* cell wall, whole cells and extra cellular products by affinity chromatography on fibrinogen linked Sepharose 4B but not from sonicated preparations of *S.epidermidis*. The components bind to human fibrinogen and inhibit the fibrinogen induced clumping factor. Appendix A specifically teaches the fibrinogen binding proteins (clumping factor is specific for *S. aureus*) of *S.aureus*. However, the claimed invention is drawn to collagen binding proteins. In addition, it appears that not only *S.epidermidis* but also other staphylococcal L-forms do not contain clumping factor component (fibrinogen binding protein). Therefore, the reference does not teach cross-reactive antibodies to surface antigens of *S.aureus* and *S.epidermidis*.

The examiner would like bring applicant's attention to some of the art which show the cross reaction between *S.epidermidis* and *S.aureus* using antibody/antigen reference system by

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Schiotz et al *Acta.Pathol Microbiol Scand* 1979, 87(6) 329-36 and Espersen et al (*Acta.Pathol Microbiol Scand* 1981, 89:253-260).

Schiotz et al disclose cross reactive rabbit antibody raised against 55 antigens found in a mixture of sonicated preparations of *S.aureus*. Twelve of *S.aureus* antigens cross-reacted with the four *S.epidermidis* biotypes (see Table 1 and Figure 3 A and B) using said polyclonal antisera (see under 102 (b) rejection). The polyclonal antibodies raised against sonicated preparations of *S.aureus* includes collagen adhesion surface antigen. Therefore, the disclosed antibodies read on the claimed cross reactive antibody.

In addition, Espersen et al (*Acta.Pathol Microbiol Scand* 1981, 89:253-260) disclose cross reactive rabbit antibody raised against 43 antigens found in a mixture of sonicated preparations of *S.epidermidis*. Fourteen of the *S.epidermidis* antigens cross-reacted with antigens of all *S.aureus* strains (see Table 3, and abstract). Thus these references teach antibodies to surface antigens of *S.aureus* cross-reacted with surface antigens of *S.epidermidis* and vice versa.

With respect to Bowden et al 2002 Appendix B (*J. Biol. Chem.* 277(45): 43017-43023), the examiner reviewed the Appendix B and understands that antibodies to CNA19 appear to bind to the extra cellular lipase enzyme originally found in *S.epidermidis* 9 as a collagen binding protein. The mature GehD circular dichroism spectra differs from that of CNA but strongly resembles that of a mammalian alpha 1 integrin I domain indicating that they have similar secondary structures. This suggests GehD is a bifunctional molecule acting not only as lipase but also as a cell surface –associated collagen adhesin (see abstract).

The examiner also reviewed the art, for example Longshaw et al *Microbiology* 2000, 146; 1419-1427 and understands that the sequence homology of mature lipase (binds to collagen I, II and IV) GehD between *S.epidermidis* and *S.aureus* is quite striking (see Figure 4

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and Table 2) and the mature lipases particularly showed high degree of conservation between S.aureus and S.epidermidis (see figure 4). Thus the reference teaches high degree of conservation between mature lipases of S.aureus and S.epidermidis and suggests they might have similar secondary structures (collagen adhesion). This indicates that these two bacteria S.aureus and S.epidermidis have common secondary conservative antigens present in collagen.

Thus, the art discloses cross-reactive antibodies between S.aureus and S.epidermidis. Further, the prior art cited by the examiner U.S.Patent 6,288,214 clearly suggests preventing bacterial adhesion using collagen specific products such as antibodies (column 43, lines 50-53, column 32, lines 40-46 and abstract). Therefore, the rejections of record are proper for this broadly claimed invention.

Claim Rejections - 35 USC 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1, 3-14, 23, 26, 29 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, the abbreviation "CNA19" is used without definition upon their first appearance in the claims.

Claim Rejections - 35 USC 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 9, 10 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schiotz et al Acta.Pathol Microbiol Scand 1979, 87(6) 329-36.

Claims are drawn to an isolated cross-reactive antibody which recognizes the CNA19 region, amino acids 151-318 of the collagen binding domain from the *S. aureus* CNA protein, wherein said antibody is cross-reactive to both *S. aureus* and *S. epidermidis*, wherein Isolated antisera containing an antibody, wherein the antibody is a polyclonal antibody and said isolated antibody that is cross-reactive to both *S. aureus* and *S. epidermidis* which is generated against the CNA19 region, amino acids 151-318 of the collagen binding domain of the *S. aureus* CNA protein.

Schiotz et al disclose polyclonal antibody (Ref.Ab) preparation consisted of purified immunoglobulins, isolated from pooled rabbit antisera immunized with a mixture of sonicated preparations (containing 55 antigens) of *S. aureus* (see page 330, right column, last paragraph through page 331, left column first paragraph) said antibody is polyclonal, said antisera contains antibody. All 12 antigens of the *S. aureus* cross reacted with all four biotypes of *S. epidermidis* (see Table 1, and figure 3A and B) using said *S. aureus* antibody. The cross-reactive antibody was generated against sonicated antigens from *S. aureus* that includes CAN-19 region. Thus

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the prior art anticipated the claimed invention.

14. Claims 1, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Espersen et al Acta.Pathol Microbiol Scand 1981, 89:253-260.

Claims are drawn to an isolated cross-reactive antibody which recognizes the CNA19 region, amino acids 151-318 of the collagen binding domain from the *S. aureus* CNA protein, wherein said antibody is cross-reactive to both *S. aureus* and *S. epidermidis*, wherein Isolated antisera containing an antibody, wherein the antibody is a polyclonal antibody

Esperisen et al disclose polyclonal antibody (Ref.Ab) preparation consisted of purified immunoglobulins, isolated from pooled rabbit antisera immunized with a mixture of sonicated preparations of *S.epidermidis*, said antibody is polyclonal, said antisera contains antibody. (see page 254, left column, third paragraph). Fourteen of the *S.epidermidis* antigens cross-reacted with antigens of all *S.aureus* strains (see Table 3, and abstract) using said antibody. As this antibody recognizes antigens of all *S.aureus* strains that includes CNA19 region.

15. Claims 1, 3-14, 23, 26, 29 -32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hook et al 2001 (U.S.Patent 6,288,214).

The disclosed antibodies to SEQ.ID.NO: 6 of the Patent (see claims) bind to amino acids 30-531 of the full length CNA protein. Therefore, these antibodies bind to CNA 19 peptide of the present application that contains amino acids 151-318 of the full length CNA protein and prevent *S.aureus* infection. Further, the antibodies disclosed in the patent are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat *S.aureus* infection (see abstract, figures 5-7 and columns 15-19). Further the prior art discloses antibodies that prevent *S.aureus* infection (i.e., antibody capable of displacing *S.aureus* to collagen, see figures 7- 8) and other related bacterial colonies (column 4, lines 45-50). Therefore, the disclosed antibodies are cross-reactive to *S.epidermidis*. The prior art also discloses diagnostic kits

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comprising the antibodies (column 26).

16. Claims 1, 3-14, 23, 26, 29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hook et al WO97/43314 20 November 1997 (20.11.1997).

Hook et al., disclose the 19,000 M collagen-binding domain from *Staphylococcus aureus*, also known as CNA-19. The 19kda protein contains the 168 amino acid long segments, specifically amino acids 151-318 of the protein that has appreciable collagen binding activity (page 3). Hook et al., disclose the preparation of immunological compositions such as anti-collagen binding protein (CBP) antibodies for diagnostic and therapeutic methods relating to the detection and treatment of infections caused by *S. aureus* and related gram-positive species (page 16). The antibody compositions are disclosed which bind to site-specifically altered proteins, and specific native and synthetically mutated CBP with domain specific epitopes within the CBPs (page 16). The antibodies have been developed to inhibit collagen binding to CBP and *S.aureus* binding to extracellular matrix in both in vitro and in vivo (page 26 and claims). Hence the antibodies are capable of displacing *S.aureus* bound to an extracellular protein. The antibodies may be monoclonal, or polyclonal (page 26 and claims) and interact with collagen binding domain of a staphylococcal *cna* gene product (claim 1). Therefore, the antibodies could cross react with *S.epidermis*. The vaccine formulation are useful against streptococcal and staphylococcal infection (page 29). The therapeutic and diagnostic kits comprising CBP compositions include antibodies and labels (page 37-39). The administration of antibodies reactive with CBP to at-risk subjects will be effective for prophylaxis of and in the case of infected subjects for therapy of bacterial infections (page 17). Preferred animals to receive treatment include mammals and particularly humans (page 18). Also taught were immunoassays for detection in ELISA plates, dot blots and western analysis (page 20). Exemplary samples include clinical samples of blood and serum (page 21). Also taught are

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methods for inhibiting bacterial adhesion to collagen (page 22). Therefore, in the absence of evidence to the contrary the disclosed antibodies against CNA19 can perform the same functions as recited by the instant claims and thus anticipated the claimed invention.

17. Claims 1, 3-14, 23, 26 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Patti et al (Journal of Biological Chemistry. May 1995, Vol, 270. No 20, pages 12005-12011).

Patti et al disclose polyclonal antibodies raised against collagen binding MSCRAMMs. The polyclonal antibodies bind to CNA peptides (figure 1) and have been shown to inhibit collagen binding of S.aureus (figures 2 and 3). Since these antibodies inhibit the binding of S.aureus, these antibodies are capable of displacing S.aureus bound to collagen (pages 12007-12010). Antibodies suitable for administration of parenteral, oral etc for treating and preventing S. aureus are considered as intended use of these antibodies. . A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to an intended use must result in a manipulative difference as compared to the prior art. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention. . In the absence of evidence to the contrary the disclosed prior art antibodies and the claimed antibodies are same. Since the Office does not have the facilities for examining and comparing applicants' antibodies and with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

18. Claims 1, 3 -14, 23, 26 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated

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by Patti et al (Journal of Biological Chemistry. May 1992, Vol, 267. No 7, pages 4764-4772).

Patti et al disclose monospecific (page 4766, right column 2nd paragraph) and polyclonal antibodies (see figure 4 legend) raised against native collagen from S.aureus (page 4766, right column 2nd paragraph). These anti-receptor antibodies bind to collagen (figure 7) and have been shown to inhibit collagen binding of S.aureus (figures 6). Since these antibodies inhibit the binding of S.aureus, these antibodies are capable of displacing S.aureus bound to collagen.

Antibodies suitable for administration of parenteral, oral etc for treating and preventing S. aureus are considered as intended use of these antibodies. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to an intended use must result in a manipulative difference as compared to the prior art. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention. In the absence of evidence to the contrary the disclosed prior art antibodies and the claimed antibodies are same. Since the Office does not have the facilities for examining and comparing applicants' antibodies and with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Remarks

19. No claims are allowed.

Conclusion

20. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989.

21. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


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